DEC 1 2 2011

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K113181

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1. Submitter name, address, contact	Veridex, LLC 1001 U.S. Route 202 Raritan, NJ 08869 Contact Person: Patricia Hojnoski
2. Preparation Date	Date Special 510(k) prepared: October 27, 2011
3. Device name	Trade or Proprietary Name: CellTracks Analyzer II® Common Name: System, immunomagnetic, circulating cancer cell, enumeration Classification Name: Immunomagnetic circulating cancer cell selection and enumeration system. (21 CFR 866.6020, Product Code NQI)
4. Predicate device	The predicate device is the CellTracks Analyzer II® (K060110, March 16, 2006)

5. Device Description

The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope, consisting of the analyzer, a dedicated computer with CELLTRACKS® software, monitor, keyboard, mouse and uninterruptible power supply (UPS). Use of this product requires training and should be used under the supervision of laboratory management.

The CELLTRACKS ANALYZER II® is for analysis of rare cells that are isolated from biological fluids including whole blood. It is used in conjunction with the CELLTRACKS® AUTOPREP® System, which automates and standardizes the sample preparation with specific reagent kits.

6. Device intended use

The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immunomagnetically selected and aligned. This product is for *in vitro* diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for *in vitro* diagnostic use with this device.

7. Comparison to predicate device

The CellTracks Analyzer II® (modified) is substantially equivalent to the CellTracks Analyzer II® (K060110: March 16, 2006). There has been no change to intended use, fundamental scientific technology, mode of operations, or specimen type/identification. All of the algorithms associated with image acquisition, analysis, cell selection, review, reporting and archiving and the logic and interface to the PC remain the same.

Changes from the predicate include:

Upgrade from version 2.4 software to version 2.5.0 software:

The software will include the following design changes:

-- Updated version of the operating system to support future hardware changes

-- Solutions to software anomalies

-- New features to enhance customer satisfaction

-- Software text string translations to Danish

8. Conclusions

The information presented in the premarket notification demonstrates that the performance of the CellTracks Analyzer II® (modified) is substantially equivalent to the predicate device.

Equivalence was demonstrated through software verification and validation.

The information presented in the premarket notification provides assurance that the CellTracks Analyzer II® (modified) is safe and effective for the stated intended use. No new issues of safety or effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Veridex, LLC
c/o Patricia M. Hojnoski, MS, RAC
Manager, Regulatory Affairs
1001 US Highway 202 North
Raritan, NJ 08869

DEC 1 2 2011

Re: k113181
Trade Name: CellTracks Analyzer II®
Regulation Number: 21 CFR §866.6020
Regulation Name: Immunomagnetic circulating cancer cell selection and enumeration system
Regulatory Class: Class II
Product Code: NQI
Dated: November 28, 2011
Received: November 29, 2011

Dear Ms. Hojnoski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113181

Device Name: CellTracks Analyzer II®

Indications For Use:

The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immunomagnetically selected and aligned. This product is for *in vitro* diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for *in vitro* diagnostic use with this device.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113181